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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,793	06/13/2000	Jiangchun Xu	210121.427C15	5630

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	29

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/593,793	XU ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20,22 and 61-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20,22 and 61-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/24/2003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2003 has been entered.

2. Claims 19, 20, 22 and 61-65 are pending and under examination.

Specification

3. If applicant desires priority under 35 U.S.C. 119(e), 120, 121 and 365(c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent applications (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now

abandoned" should follow the filing date of the parent application. It is requested that applicant update the status of all U.S. application numbers in the priority statement.

See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) "Benefit of Prior-Filed Application".

4. The disclosure is objected to because of the following informalities:

a. U.S. Application number 09/020,956 disclosed on page 138, line 4 is now U.S. Patent 6,261,562. Applicant is requested to update the specification with the U.S. Patent number.

b. Applicant is requested to update the status of U.S. Application number 08/700,014 disclosed on page 152, line 6 as now abandoned.

c. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 182, lines 1-2. Applicant is required to check the entire disclosure and delete all the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 64 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

7. Claims 64 and 65 are indefinite for reciting "an antigen-presenting cell that expresses a polypeptide...", wherein the polypeptide may be (a) SEQ ID NO:113 or (c) sequences having at least 90% identity to SEQ ID NO:113 according to claim 64. It is unclear if the entire sequence of SEQ ID NO:113 is used or only peptides of SEQ ID NO:113. The initial activation of a T cell usually occurs when it recognizes a foreign peptide of about 8-12 amino acids long bound to an MHC molecule on the surface of an antigen-presenting cell. Do the antigen-presenting cells process SEQ ID NO:113? Do the antigen-presenting cells express the entire SEQ ID NO:113 or do they express the processed peptides bound to an MHC molecule? Further, are the sequences having at least 90% identity to SEQ ID NO:113 compared to the entire length of SEQ ID NO:113 or are the sequences 90% identical to at least a 10 amino acid portion of SEQ ID NO:113?

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 61, 19, 20, 22, 63, 62, 64 and 65 are rejected under 35 U.S.C. as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an immunogenic composition comprising an immunostimulant and an antigen presenting cell expressing a polypeptide having at least 90% amino acid identity to SEQ ID NO:113 wherein the polypeptide is capable of stimulating a human T lymphocyte response and a method of stimulating an immune response with said composition. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that are defined only by length and/or sequence identity.

The claims encompass variants and portions of SEQ ID NO:113, which are insufficiently defined in the specification as polypeptides which contain substitutions ect. (see pages 55-59) as long as they maintain the immunogenicity of the unaltered polypeptide (SEQ ID NO:113). The specification provides insufficient written description to support the broad genus of variants encompassed by the claims. The portions of SEQ ID NO:113 directed to such immunogenic portions in said sequence lack written description of what sequences are present therein (i.e., specific T cell epitopes). Further, the disclosure provides insufficient identifying and functional characteristics to distinguish the claimed polypeptide variants (i.e., 90% identity to SEQ ID NO:113 and

90% identity to at least a 10 amino acid portion of SEQ ID NO:113) and portions of SEQ ID NO:113 from just any polypeptide 90% identical to SEQ ID NO:113, capable of stimulating a human cytotoxic T lymphocyte response.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Per the *Enzo* court's example of a description of an anti-inflammatory steroid couched "in terms of its function of lessening inflammation of tissues," which, the court stated, "fails to distinguish any steroid from others having the same activity or function," and which therefore, fails to satisfy the written-description requirement. Similarly, "a polypeptide comprising at least a 10 amino acid portion of SEQ ID NO:113 or a composition comprising an antigen-presenting cell that expresses SEQ ID NO:113 or variant (i.e. at least 90% identity) or portion thereof (i.e., at least 10 amino acids) that are capable of stimulating a human T lymphocyte response" does not distinguish SEQ ID NO:113 or variants or portions thereof from just any other amino acid sequence

having the same activity or function (i.e., capable of stimulating a human T lymphocyte response) and as such, does not satisfy the written-description requirement. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

10. Claims 61, 19, 20, 22 and 63-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions and methods for treating prostate cancer comprising an immunostimulant and the prostate-specific polypeptide of SEQ ID NO:113 or a prostate-specific polypeptide portion of SEQ ID NO:113 comprising the P1S#10 peptide (SEQ ID NO:337), does not reasonably provide enablement for immunogenic compositions and methods for treating any cancer comprising just any polypeptide of SEQ ID NO:113 at least 10 amino acids in length or polypeptides having less than 100% amino acid identity to SEQ ID NO:113 or antigen-presenting cells expressing the entirety of SEQ ID NO:113 or just any amino acid portion of SEQ ID NO:113 greater than 10 amino acids in length or sequences having at least 90% identity to the entirety of SEQ ID NO:113, wherein the polypeptide is capable of stimulating a human T lymphocyte response for the treatment of any cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in

the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least a 10 amino acid portion of SEQ ID NO:113 or a polypeptide having at least 90% amino acid identity to SEQ ID NO:113 or an antigen presenting cell expressing the entirety of SEQ ID NO:113 or a polypeptide comprising at least a 10 amino acid portion of SEQ ID NO:113 or a polypeptide having at least 90% amino acid identity to the entirety of SEQ ID NO:113 or 90% identity to at least a 10 amino acid portion of SEQ ID NO:113, wherein the polypeptide is capable of stimulating a human T lymphocyte response and methods of stimulating an immune response with said compositions for the treatment of any cancer. The specification teaches that the cDNA (L1-12) (SEQ ID NO:110) encoding SEQ ID NO:113 was isolated from a prosate tumor cDNA library (see pages 125-126) and its corresponding mRNA was shown to be specifically over-expressed in prostate tumor and normal prostate, but at low to undetectable levels in all other tissues examined including breast, colon and lung tumors (see page 129, lines 16-28). Additionally, the specification teaches, on page 144 line 19 to page 145, line 5, that SEQ ID NO:337, a 9-mer peptide derived from clone L1-12 (SEQ ID NO:113) is capable of stimulating T-cells. The specification further discloses, on page 12 that SEQ ID NO:110 is the full-length cDNA of L1-12 (also referred to as P501S) and that SEQ ID NO:110 encodes SEQ ID NO:113.

The 9-mer represented by SEQ ID NO:337 corresponds to residues 367-375 of SEQ ID NO:113, therefore one skilled in the art would reasonably conclude that a polypeptide comprising residues 367-375 of SEQ ID NO:113 would be a polypeptide comprising an amino acid sequence capable of stimulating human T-cells. The state of the prior art is such that it is well known that epitopes from a polypeptide must interact with T-cell receptors or be presented on the surface of antigen-presenting cells in association with MHC molecules in order to stimulate T-cells. While it is known that size is a factor in processing and recognition of an epitope, it is also known that other factors are involved in T cell stimulation, all of which have not been elucidated. For support, see Bixler et al (U.S. patent 5,785,973, column 5, line 47 to column 7, line 59). The prior art of Geysen (U.S. Patent 5,539,084) shows that even for peptides of similar size derived from the same "parent" polypeptide, not all will be capable of interacting with T-cells (column 2, lines 5-9 and Figure 6), thus demonstrating the degree of uncertainty in the art for predicting which subsets or portions of a larger polypeptide will be capable of interacting with or stimulating T-cells. Neither the specification nor the prior art teach specific T cell epitopes of SEQ ID NO:113 other than the P1S#10 peptide (SEQ ID NO:337), which are known to be capable of stimulating T-cells. The level of skill in the art is acknowledged to be high, however, due to the high degree of uncertainty in predicting what portions of SEQ ID NO:113 greater than 10 amino acids in length would be expected or capable of stimulating T-cells, and the lack of teaching in the specification as to what portions of SEQ ID NO:113 are known to be capable of stimulating T-cells, it would require undue experimentation by one skilled in the art to determine which

portions or variants of SEQ ID NO:113 greater than 10 amino acids in length that are capable of stimulating T-cells.

Priority

11. The instant application appears to be a CIP of several previous applications. The filing date of instant claims 61, 19, 22 and 62 is deemed to be the filing date of USSN 09/115,453, (now U.S. Patent 6,657,056), i.e., 6/14/1998 (see column 3, lines 37-39 and column 4, line 1 and column 6, lines 58-67 and column 7, lines 16-24). Instant claims 20 and 63-65 are deemed to be the filing date of USSN 09/352,616 (now U.S. Patent 6,395,278) i.e., 6/13/1999 (see column 2, line 20 and column 32, lines 66-67 and column 33, lines 1-33, 59-67 and column 34). It is acknowledged that USSN 09/020,956 (now U.S. Patent 6,261,562) appears to provide support for the combined composition comprising SEQ ID NO:113 (not at least a 10 amino acid portion of SEQ ID NO:113) and an adjuvant wherein the adjuvant may be lipid A and a method of stimulating an immune response in a patient comprising said composition, however, support for the narrower limitations of the instant claims can not be found. Priority applications USSNs 09/030,607 (now U.S. Patent 6,262,245), 09/020,956 (now U.S. Patent 6,261,562), 08/904,804 and 08/806,099 do not apparently support compositions and methods comprising the combination of an immunostimulant and (i) at least a 10 amino acid portion of SEQ ID NO:113 or (ii) a polypeptide having at least 90% identity to SEQ ID NO:113 or (iii) an antigen-presenting cell expressing any one of (1) SEQ ID

NO:113, or (2) at least a 10 amino acid portion of SEQ ID NO:113, or (3) sequences having at least 90% identity to SEQ ID NO:113. If applicant desires priority prior to 6/14/1998 (claims 61, 19, 22 and 62) or 6/13/1999 (claims 20 and 63-65); applicant is invited to specifically point out and provide documentary support for the priority of the instant claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 61, 19, 20, 22, 63 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Billing-Mendel et al (U.S. Patent 6,130,043, filing date of parent case 08/850,713, 5/2/1997, Ids filed as paper #26, 1/24/2003) as evidenced by the instant disclosure in view of Hauser et al (U.S. Patent 5,776,468, 102(e) date 2/12/1996) and Ladd et al (U.S. Patent 5,759,551, 102(e) date 12/26/1995).

Claims 61, 19, 20, 63 and 62 recite an immunogenic composition comprising an immunostimulant and at least a 10 amino acid portion of SEQ ID NO:113 or a polypeptide having at least 90% identity to SEQ ID NO:113 capable of stimulating a human cytotoxic T lymphocyte response, wherein the immunostimulant is selected from an adjuvant, monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A or saponins.

It is acknowledged that Billing-Mendel teach a polypeptide of 255 amino acids, which shares 100% amino acid identity with residues 299-553 of the instantly claimed SEQ ID NO:113 (see the attached sequence alignment). However, the parent application USSN 08/850,713 only discloses a polypeptide of 242 amino acids (SEQ ID NO:19), which shares 100% amino acid identity with residues 299-529 of the instantly

claimed SEQ ID NO:113. Therefore, this rejection applies only to residues 299-529 of instantly claimed SEQ ID NO:113 as set forth below.

Billing-Mendel teach a polypeptide of 242 amino acids (SEQ ID NO:36), which shares 100% amino acid identity with residues 299-529 of the instantly claimed SEQ ID NO:113 (see alignment attached to the back of this office action) and Billing-Mendel et al teach that the polypeptide of SEQ ID NO:36 is encoded by the polynucleotide of SEQ ID NO:16 (see column 41, lines 18-25). The amino acid sequence (sequence 36) is also encoded by nucleotides 1178-1943 of the instantly claimed SEQ ID NO:110 (see the attached sequence alignment). As evidenced by the instant disclosure SEQ ID NO:110 is the full-length cDNA of L1-12 (also referred to as P501S) and SEQ ID NO:110 encodes the instantly claimed SEQ ID NO:113 (see page 12). Billing-Mendel et al teach polyclonal and monoclonal antibodies made with the polypeptide of sequence 36, thus the polypeptide is immunogenic (see columns 57-60) and Billing-Mendel teach administration in the presence of complete or incomplete Freund's adjuvant (see column 57, lines 48-59). The instant disclosure teaches, on page 144 line 19 to page 145, line 5, that SEQ ID NO:337, a 9-mer peptide composed of residues 367-375 of SEQ ID NO:113 is capable of stimulating T-cells. As a property is inherent to a product, any sequence comprising this 9-mer would be expected to be capable of stimulating T-cells. Thus, Billing-Mendel et al teach a polypeptide (sequence 36) that includes residues 367-375 of SEQ ID NO:113 (see alignment attached to the back of this office action). Billing-Mendel et al do not specifically teach an adjuvant selected from the group consisting of monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A,

and saponins wherein the adjuvant induces a Type I response. This deficiency is made up for in the teachings of Hauser et al and Ladd et al.

Hauser et al teach an improved adjuvant, small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response (column 18, lines 5-30 and column 28, lines 1-10).

Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin (see column 17, lines 1-4).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Billing-Mendel et al and Hauser et al and Ladd et al because Billing-Mendel et al teach a polypeptide which includes residues 351-472 of SEQ ID NO:113 and shares 100% amino acid identity with SEQ ID NO:113 over this stretch. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of

success to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Billing-Mendel et al and Hauser et al and Ladd et al because Hauser et al teach immunogenic compositions comprising small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response and Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin. Thus, it would have been obvious to one skilled in the art to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Billing-Mendel et al and Hauser et al and Ladd et al.

14. Claims 61, 19, 20, 22, 63 and 62 are rejected under 35 U.S.C. 103(a) as being obvious over Xu et al (U.S. Patent 6,261,562, filed 2/9/1998) as evidenced by the instant disclosure in view of Hauser et al (U.S. Patent 5,776,468, 102(e) date 2/12/1996) and Ladd et al (U.S. Patent 5,759,551, 102(e) date 12/26/1995).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claims have been described supra.

Xu et al teach a polypeptide comprising SEQ ID NO:113 and a non-specific immune response enhancer, wherein the enhancer can be an adjuvant and the adjuvant may comprise lipid A. Residues 1-553 of SEQ ID NO:113 recited in the Xu Patent (U.S. Patent 6,261,562) share 100% amino acid identity with the instantly claimed SEQ ID NO:113 (see alignment attached to the back of this office action). The instant disclosure teaches, on page 144 line 19 to page 145, line 5, that SEQ ID NO:337, a 9-mer peptide composed of residues 367-375 of SEQ ID NO:113 is capable of stimulating T-cells. As a property is inherent to a product, any sequence comprising this 9-mer

would be expected to be capable of stimulating T-cells. Thus, it is obvious that Xu's polypeptide of SEQ ID NO:113 recited in U.S. Patent No. 6,261,562 when combined with an adjuvant and/or lipid A in a composition is equally immunogenic and equally capable of stimulating a human T lymphocyte response, as it shares 100% amino acid identity with the instantly claimed SEQ ID NO:113 and comprises residues 367-375 of the instantly claimed SEQ ID NO:113. Xu et al also teach adjuvant species (i.e., Freund's Incomplete Adjuvant; Freund's Complete Adjuvant and Merck Adjuvant 65) , which anticipate the instantly claimed genus (i.e., adjuvant). Xu et al do not specifically teach immunostimulants consisting of monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins. This deficiency is made up for in the teachings of Hauser et al and Ladd et al.

Hauser et al has been described supra.

Ladd et al has been described supra.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A;

3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Xu et al as evidenced by the instant disclosure and further in view of Hauser et al and Ladd et al because Xu et al teach a polypeptide which includes residues 1-553 of the instantly claimed SEQ ID NO:113 and shares 100% amino acid identity with SEQ ID NO:113 over this stretch and Xu et al combine SEQ ID NO:113 with an adjuvant (i.e., non-specific immune response enhancer). In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Xu et al and Hauser et al and Ladd et al because Hauser et al teach immunogenic compositions comprising small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response and Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin. Thus, it would have been obvious to one skilled in the art to have produced an immunogenic composition comprising an immunostimulant and a polypeptide comprising at least 10 amino acids of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Xu et al as evidenced by the instant disclosure and further in view of Hauser et al and Ladd et al.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 61, 19, 20, 22, 63 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-7 and 13 of U.S. Patent No. 6,261,562, filed 2/9/1998 in view of Hauser et al (U.S. Patent 5,776,468, 102(e) date 2/12/1996) and Ladd et al (U.S. Patent 5,759,551, 102(e) date 12/26/1995). Although the conflicting claims are not identical, they are not patentably distinct from each other.

It is noted that a restriction requirement was made in the instant application and parent application USSN 09/020,956 (now U.S. Patent 6,261,562). Because the invention in U.S. Patent 6,261,562 and the invention in the instant application were restricted to the same Group (i.e, Group I, isolated polypeptides, SEQ ID NO:113), a double patenting rejection in the instant application is proper.

The instant claims are drawn to an immunogenic composition comprising an immunostimulant and at least a 10 amino acid portion of SEQ ID NO:113 or a polypeptide having at least 90% identity to SEQ ID NO:113 capable of stimulating a human cytotoxic T lymphocyte response, wherein the immunostimulant is selected from an adjuvant, monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A or saponins and a method of stimulating an immune response in a patient by administering said composition.

Claims 1, 4-7 and 13 of U.S. Patent No. 6,261,562 are drawn towards a polypeptide comprising SEQ ID NO:113 and a non-specific immune response enhancer, wherein the enhancer can be an adjuvant and the adjuvant may comprise lipid A. Residues 1-553 of SEQ ID NO:113 recited in U.S. Patent 6,261,562 share 100% amino acid identity with the instantly claimed SEQ ID NO:113 (see alignment attached to the back of this office action). As a property is inherent to a product, it is obvious that Hauser's polypeptide of SEQ ID NO:113 recited in U.S. Patent No. 6,261,562 when combined with an adjuvant and/or lipid A in a composition is equally immunogenic and equally capable of stimulating a human T lymphocyte response, as it shares 100% amino acid identity with the instantly claimed SEQ ID NO:113. The adjuvant species (i.e., Freund's Incomplete Adjuvant; Freund's Complete Adjuvant and Merck Adjuvant 65) recited in claim 7 of U.S. Patent 6,261,562 anticipate the genus (i.e., adjuvant) recited in claim 19 in the instant application. Thus, a patent to the genus would, necessarily, extend the rights of the species should the genus issue as a patent. The claims in U.S. Patent 6,261,562 do not teach immunostimulants consisting of

monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins. This deficiency is made up for in the teachings of Hauser et al and Ladd et al.

Hauser et al teach an improved adjuvant, small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response (column 18, lines 5-30 and column 28, lines 1-10).

Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin (see column 17, lines 1-4).

The claims in the instant application are obvious variants of U.S. Patent 6,261,562 because it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunogenic compositions comprising an immunostimulant and a polypeptide portions of greater than 10 amino acids of SEQ ID NO:113 or a polypeptide having at least 90% identity to SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic compositions comprising an immunostimulant and a polypeptide portions of greater than 10 amino acids of SEQ ID NO:113 or a polypeptide having at least 90% identity to SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Hauser et al and Ladd et al because Hauser et al teach small monophosphoryl lipid A, which

preferentially induces IgG2a, and induces a Type I response and Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin.

Claims 61, 19, 20, 22, 63 and 62 directed to an invention not patentably distinct from claims 1, 4-7 and 13 of commonly assigned U.S. Patent No. 6,261,562. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent. 6,261,562, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

17. Claims 61, 19, 20, 63 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,329,505 B1 filed 11/12/1999 in view of Hauser et al (U.S. Patent 5,776,468, 102(e) date 2/12/1996) and Ladd et al (U.S. Patent 5,759,551, 102(e) date 12/26/1995). Although the conflicting claims are not identical, they are not patentably distinct from each other.

It is noted that a restriction requirement was made in the instant application and in parent application USSN 09/439,313 (now U.S. Patent 6,329,505 B1). Because the invention in U.S. Patent 6,329,505 B1 and the invention in the instant application were restricted to the same Group (i.e., Group I, isolated polypeptides, SEQ ID NO:113), a double patenting rejection in the instant application is proper.

The instant claims are drawn to an immunogenic composition comprising an immunostimulant and at least a 10 amino acid portion of SEQ ID NO:113 or a polypeptide having at least 90% identity to SEQ ID NO:113 capable of stimulating a human cytotoxic T lymphocyte response, wherein the immunostimulant is selected from an adjuvant, monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A or saponins.

Because claims 1-5 of U.S. Patent 6,329,505 B1 are drawn to certain species of SEQ ID NO:113 that are at least 10 amino acids in length and the instant claims are drawn to the genus (i.e., any amino acid portion of SEQ ID NO:113 at least 10 amino acids in length) the claims in U.S. Patent 6,329,505 B1 anticipate the instant claims. Claims 1-5 of U.S. Patent No. 6,329,505 B1 are drawn towards isolated polypeptide

portions of SEQ ID NO:113, selected from the group consisting of SEQ ID Nos. 554 (19-mer), 558 (12-mer) and 562 (16-mer), an isolated polypeptide comprising at least a portion of a sequence having at least 90% or 95% identity to the entirety of SEQ ID NO:113 or to a sequence selected from the group consisting of SEQ ID Nos. 554 (19-mer) (residues 38-53 of instantly claimed SEQ ID NO:113), 558 (12-mer) (residues 110-121 of instantly claimed SEQ ID NO:113), 562 (16-mer) (residues 182-197 of instantly claimed SEQ ID NO:113), 566 (27-mer) (residues 296-322 of instantly claimed SEQ ID NO:113) and 573 (10-mer) (residues 510-519 of instantly claimed SEQ ID NO:113). SEQ ID NO:113 recited in U.S. Patent 6,329,505 B1 as well as portions thereof (i.e., SEQ ID Nos. 554, 558, 562, 566, and 573) share 100% amino acid identity with the instantly claimed SEQ ID NO:113 (see alignment attached to the back of this office action). As a property is inherent to a product, it is obvious that the polypeptide of SEQ ID NO:113 and portions thereof recited in U.S. Patent No. 6,329,505 B1 when combined with an adjuvant and/or lipid A in a composition are equally immunogenic and equally capable of stimulating a human T lymphocyte response, as they share 100% amino acid identity with the instantly claimed SEQ ID NO:113. The claims in U.S. Patent 6,329,505 B1 do not teach immunostimulants consisting of adjuvants, monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins. This deficiency is made up for in the teachings of Hauser et al and Ladd et al.

Hauser et al teach an improved adjuvant, small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response (column 18, lines 5-30 and column 28, lines 1-10).

Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin (see column 17, lines 1-4).

The claims in the instant application are obvious variants of U.S. Patent 6,329,505 B1 because it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced an immunogenic compositions comprising an immunostimulant and a polypeptide portions of greater than 10 amino acids of SEQ ID NO:113 or a polypeptide having at least 90% identity to the entirety or to portions of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced an immunogenic compositions comprising an immunostimulant and a polypeptide portions of greater than 10 amino acids of SEQ ID NO:113 or a polypeptide having at least 90% identity to the entirety or to portions of SEQ ID NO:113, wherein the immunostimulant is selected from monophosphoryl lipid A; 3-de-O-acylated monophosphoryl lipid A; and saponins for therapeutic benefit in view of Hauser et al and Ladd et al because Hauser et al teach small monophosphoryl lipid A, which preferentially induces IgG2a, and induces a Type I response and Ladd et al teach immunogenic peptide compositions useful for the treatment of prostate cancer and these peptides can be formulated with adjuvants including saponin.

Claims 61, 19, 20, 63 and 62 are directed to an invention not patentably distinct from claims 1-5 of commonly assigned U.S. Patent 6,329,505 B1. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent 6,329,505 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

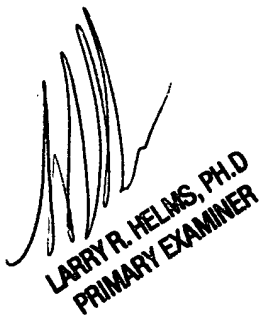
Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827



RESULT 7
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; Patent No. 6130043
; GENERAL INFORMATION:
; APPLICANT: BILLING-MEDEL, PATRICIA
; APPLICANT: COHEN, MAURICE
; APPLICANT: COLPITTS, TRACEY L.
; APPLICANT: FRIEDMAN, PAULA N.
; APPLICANT: GORDON, JULIAN
; APPLICANT: GRANADOS, EDWARD N.
; APPLICANT: HODGES, STEVEN C.
; APPLICANT: KLASS, MICHAEL R.
; APPLICANT: KRATOCHVIL, JON D.
; APPLICANT: ROBERTS-RAPP, LISA
; APPLICANT: RUSSELL, JOHN C.
; APPLICANT: STROUPE, STEPHEN D.
; TITLE OF INVENTION: REAGENTS AND METHODS USEFUL
; TITLE OF INVENTION: FOR DETECTING DISEASES OF THE PROSTATE
; NUMBER OF SEQUENCES: 41
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Abbott Laboratories
; STREET: 100 Abbott Park Road
; CITY: Abbott Park
; STATE: IL
; COUNTRY: USA
; ZIP: 60064-3500
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Diskette
; COMPUTER: IBM Compatible
; OPERATING SYSTEM: DOS
; SOFTWARE: FastSEQ for Windows Version 2.0
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/09/071,710
; FILING DATE:
; CLASSIFICATION:
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: 08/850,713

; TELEPHONE: 847/935-1729
; TELEFAX: 847/938-2623
; TELEX:
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; SEQUENCE CHARACTERISTICS:
; LENGTH: 255 amino acids
; TYPE: amino acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: No. 6130043e
US-09-071-710-36

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FastDB - Fast Pairwise Comparison of Sequences
Release 5.4

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Number of sequences searched:                  1
Number of scores above cutoff:                 1

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SCORE 0   167  334  500  667  834  1001 1167 1334 1501
STDEV

                          PARAMETERS

Similarity matrix      Unitary    K-tuple                    4
   Match penalty            1    Joining penalty           30
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Cutoff score                0
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                       SEARCH STATISTICS

Scores:                  Mean       Median     Standard Deviation
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Number of scores above cutoff:            1

The scores below are sorted by initial score.
Significance is calculated based on initial score.

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The list of best scores is:
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1. US-593-110 (1-3410)
   US-09-071-710-16 Sequence 16, Application US/09071710

Sequence 16, Application US/09071710
Patent No. 6130043
GENERAL INFORMATION:
APPLICANT: BILLING-MEDEL, PATRICIA
APPLICANT: COHEN, MAURICE
APPLICANT: COLPITTS, TRACEY L.
APPLICANT: FRIEDMAN, PAULA N.
APPLICANT: GORDON, JULIAN
APPLICANT: GRANADOS, EDWARD N.
APPLICANT: HODGES, STEVEN C.
APPLICANT: KLASS, MICHAEL R.
APPLICANT: KRATOCHVIL, JON D.
APPLICANT: ROBERTS-RAPP, LISA
APPLICANT: RUSSELL, JOHN C.
APPLICANT: STROUPE, STEPHEN D.
TITLE OF INVENTION: REAGENTS AND METHODS USEFUL
TITLE OF INVENTION: FOR DETECTING DISEASES OF THE PROSTATE
NUMBER OF SEQUENCES: 41
CORRESPONDENCE ADDRESS:
ADDRESSEE: Abbott Laboratories
STREET: 100 Abbott Park Road
CITY: Abbott Park
STATE: IL
COUNTRY: USA
ZIP: 60064-3500
COMPUTER READABLE FORM:
MEDIUM TYPE: Diskette
COMPUTER: IBM Compatible
OPERATING SYSTEM: DOS
SOFTWARE: FastSEQ for Windows Version 2.0
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/09/071,710
FILING DATE:
CLASSIFICATION:
PRIOR APPLICATION DATA:
APPLICATION NUMBER: 08/850,713
FILING DATE: 02-MAY-1997
ATTORNEY/AGENT INFORMATION:
NAME: Becker, Cheryl L.
REGISTRATION NUMBER: 35,441
REFERENCE/DOCKET NUMBER: 6083.US.P1
TELECOMMUNICATION INFORMATION:
TELEPHONE: 847/935-1729
TELEFAX: 847/938-2623
TELEX:
INFORMATION FOR SEQ ID NO: 16:
SEQUENCE CHARACTERISTICS:
LENGTH: 2152 base pairs
TYPE: nucleic acid
STRANDEDNESS: single
TOPOLOGY: linear

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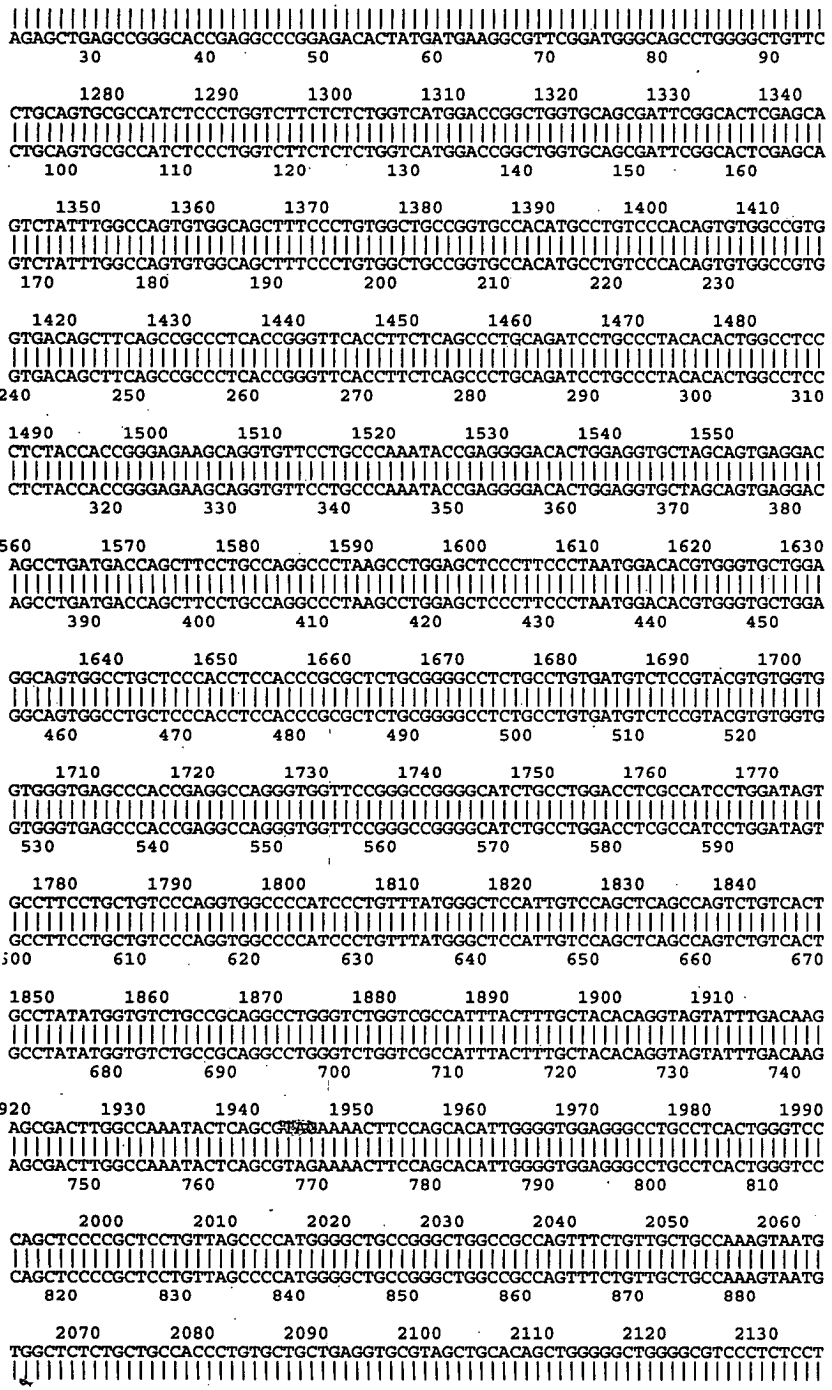
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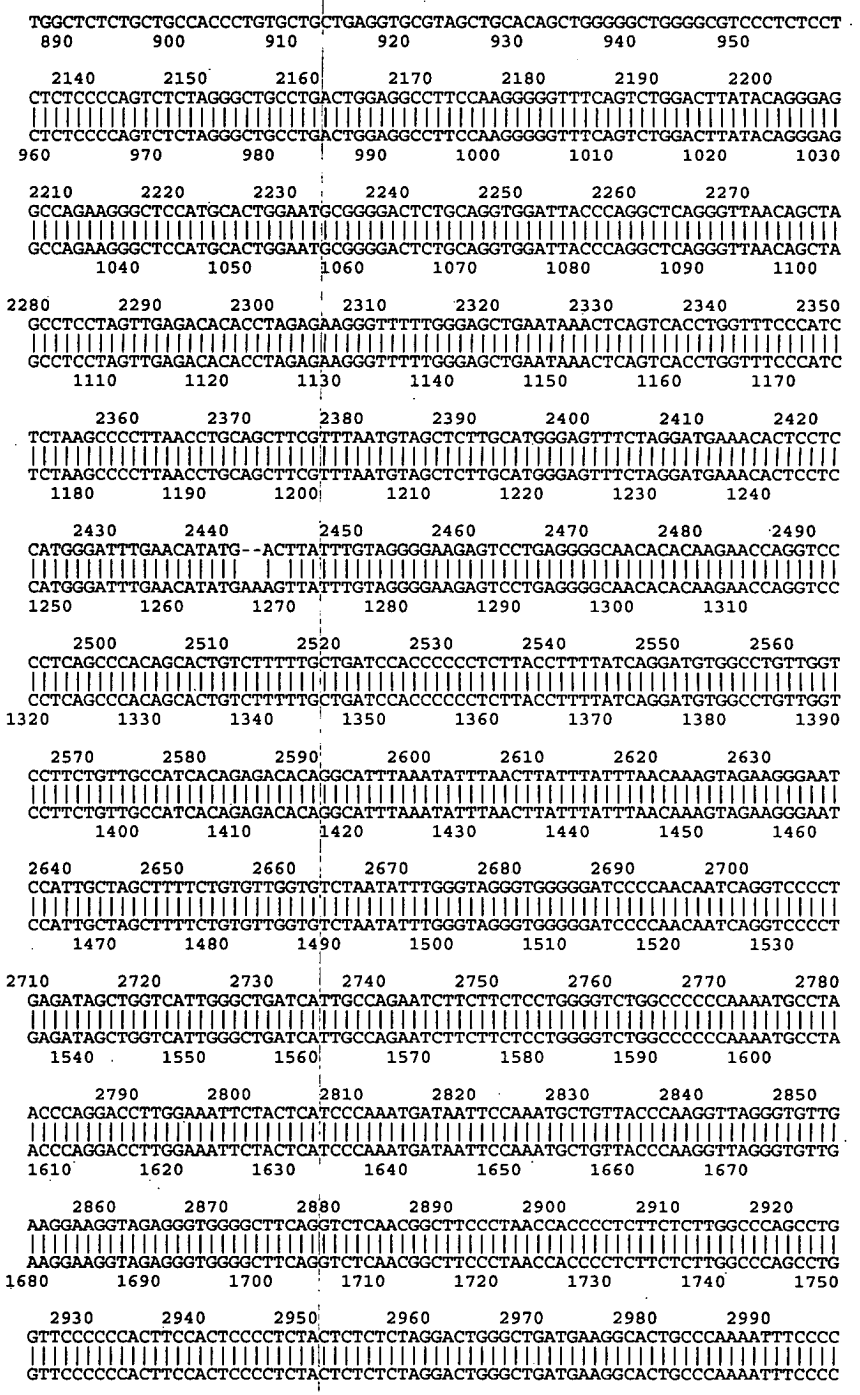
TGGCTCTCTGCTGCCACCCTGTGCTGCTGAGGTGCGTAGCTGCACAGCTGGGGGCTGGGGCGTCCCTCTCCT
890 900 910 920 930 940 950
2140 2150 2160 2170 2180 2190 2200
CTCTCCCCAGTCTCTAGGGCTGCCTGACTGGAGGCCTTCCAAGGGGGTTTCAGTCTGGACTTATACAGGGAG
CTCTCCCCAGTCTCTAGGGCTGCCTGACTGGAGGCCTTCCAAGGGGGTTTCAGTCTGGACTTATACAGGGAG
960 970 980 990 1000 1010 1020 1030
2210 2220 2230 2240 2250 2260 2270
GCCAGAAGGGCTCCATGCACTGGAATGCGGGGACTCTGCAGGTGGATTACCCAGGCTCAGGGTTAACAGCTA
GCCAGAAGGGCTCCATGCACTGGAATGCGGGGACTCTGCAGGTGGATTACCCAGGCTCAGGGTTAACAGCTA
1040 1050 1060 1070 1080 1090 1100
2280 2290 2300 2310 2320 2330 2340 2350
GCCTCCTAGTTGAGACACACCTAGAGAAGGGTTTTTGGGAGCTGAATAAACTCAGTCACCTGGTTTCCCATC
GCCTCCTAGTTGAGACACACCTAGAGAAGGGTTTTTGGGAGCTGAATAAACTCAGTCACCTGGTTTCCCATC
1110 1120 1130 1140 1150 1160 1170
2360 2370 2380 2390 2400 2410 2420
TCTAAGCCCCTTAACCTGCAGCTTCGTTTAATGTAGCTCTTGCATGGGAGTTTCTAGGATGAAACACTCCTC
TCTAAGCCCCTTAACCTGCAGCTTCGTTTAATGTAGCTCTTGCATGGGAGTTTCTAGGATGAAACACTCCTC
1180 1190 1200 1210 1220 1230 1240
2430 2440 2450 2460 2470 2480 2490
CATGGGATTTGAACATATG--ACTTATTTGTAGGGGAAGAGTCCTGAGGGGCAACACACAAGAACCAGGTCC
CATGGGATTTGAACATATGAAAGTTATTTGTAGGGGAAGAGTCCTGAGGGGCAACACACAAGAACCAGGTCC
1250 1260 1270 1280 1290 1300 1310
2500 2510 2520 2530 2540 2550 2560
CCTCAGCCCACAGCACTGTCTTTTTGCTGATCCACCCCCCTCTTACCTTTTATCAGGATGTGGCCTGTTGGT
CCTCAGCCCACAGCACTGTCTTTTTGCTGATCCACCCCCCTCTTACCTTTTATCAGGATGTGGCCTGTTGGT
1320 1330 1340 1350 1360 1370 1380 1390
2570 2580 2590 2600 2610 2620 2630
CCTTCTGTTGCCATCACAGAGACACAGGCATTTAAATATTTAACTTATTTATTTAACAAAGTAGAAGGGAAT
CCTTCTGTTGCCATCACAGAGACACAGGCATTTAAATATTTAACTTATTTATTTAACAAAGTAGAAGGGAAT
1400 1410 1420 1430 1440 1450 1460
2640 2650 2660 2670 2680 2690 2700
CCATTGCTAGCTTTTCTGTGTTGGTGTCTAATATTTGGGTAGGGTGGGGGATCCCCAACAATCAGGTCCCCT
CCATTGCTAGCTTTTCTGTGTTGGTGTCTAATATTTGGGTAGGGTGGGGGATCCCCAACAATCAGGTCCCCT
1470 1480 1490 1500 1510 1520 1530
2710 2720 2730 2740 2750 2760 2770 2780
GAGATAGCTGGTCATTGGGCTGATCATTGCCAGAATCTTCTTCTCCTGGGGTCTGGCCCCCCAAAATGCCTA
GAGATAGCTGGTCATTGGGCTGATCATTGCCAGAATCTTCTTCTCCTGGGGTCTGGCCCCCCAAAATGCCTA
1540 1550 1560 1570 1580 1590 1600
2790 2800 2810 2820 2830 2840 2850
ACCCAGGACCTTGGAAATTCTACTCATCCCAAATGATAATTCCAAATGCTGTTACCCAAGGTTAGGGTGTTG
ACCCAGGACCTTGGAAATTCTACTCATCCCAAATGATAATTCCAAATGCTGTTACCCAAGGTTAGGGTGTTG
1610 1620 1630 1640 1650 1660 1670
2860 2870 2880 2890 2900 2910 2920
AAGGAAGGTAGAGGGTGGGGCTTCAGGTCTCAACGGCTTCCCTAACCACCCCTCTTCTCTTGGCCCAGCCTG
AAGGAAGGTAGAGGGTGGGGCTTCAGGTCTCAACGGCTTCCCTAACCACCCCTCTTCTCTTGGCCCAGCCTG
1680 1690 1700 1710 1720 1730 1740 1750
2930 2940 2950 2960 2970 2980 2990
GTTCCCCCCACTTCCACTCCCCTCTACTCTCTCTAGGACTGGGCTGATGAAGGCACTGCCCAAAATTTCCCC
GTTCCCCCCACTTCCACTCCCCTCTACTCTCTCTAGGACTGGGCTGATGAAGGCACTGCCCAAAATTTCCCC

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      1760       1770       1780       1790       1800       1810       1820

   3000       3010       3020       3030       3040       3050       3060
   TACCCCCAACTTTCCCCTACCCCCAACTTTCCCCACCAGCTCCACAACCCTGTTTGGAGCTACTGCAGGACC
   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
   TACCCCCAACTTTCCCCTACCCCCAACTTTCCCCACCAGCTCCACAACCCTGTTTGGAGCTACTGCAGGACC
      1830       1840       1850       1860       1870       1880       1890

3070       3080       3090       3100       3110       3120       3130       3140
   AGAAGCACAAAGTGCGGTTTCCCAAGCCTTTGTCCATCTCAGCCCCCAGAGTATATCTGTGCTTGGGGAATC
   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
   AGAAGCACAAAGTGCGGTTTCCCAAGCCTTTGTCCATCTCAGCCCCCAGAGTATATCTGTGCTTGGGGAATC
     1900       1910       1920       1930       1940       1950       1960

         3150       3160       3170       3180       3190       3200       3210
   TCACACAGAAACTCAGGAGCACCCCCTGCCTGAGCTAAGGGAGGTCTTATCTCTCAGGGGGGGTTTAAGTGC
   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
   TCACACAGAAACTCAGGAGCACCCCCTGCCTGAGCTAAGGGAGGTCTTATCTCTCAGGGGGGGTTTAAGTGC
   1970       1980       1990       2000       2010       2020       2030

      3220       3230       3240       3250       3260       3270       3280
   CGTTTGCAATAATGTCGTCTTATTTATTTAGCGGGGTGAATATTTTATACTGTAAGTGAGCAATCAGAGTAT
   ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
   CGTTTGCAATAATGTCGTCTTATTTATTTAGCGGGGTGAATATTTTATACTGTAAGTGAGCAATCAGAGTAT
2040       2050       2060       2070       2080       2090       2100       2110

     3290       3300       3310       3320       3330       3340       3350
   AATGTTTATGGTGACAAAATTAAAGGCTTTCTTATATGTTTAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA
   ||||||||||||||||||||||||||||||||||||||||
   AATGTTTATGGTGACAAAATTAAAGGCTTTCTTATATGTTTA
        2120       2130       2140       2150 X

   3360       3370
   AAAAAAAAAAAARAAAAAAA
```

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> O <
O| |O  IntelliGenetics
> O <

FastDB - Fast Pairwise Comparison of Sequences
Release 5.4

Results file us-593-113.res made by bshears on Thu 29 Jan 104 12:32:29-PST.


Query sequence being compared:  US-593-113 (1-553)
Number of sequences searched:                    1
Number of scores above cutoff:                   1

      Results of the initial comparison of US-593-113 (1-553) with:
        File : /home/bshears/blanc*pep

    100-
      -
      -
U    50-
M     -
B     -
E     -
R     -
      -
O     -
F    10-
      -
S     -
E     5-
Q     -
U     -
E     -
N     -
C     -
E     -                                                              *
S     0----------------------------------------------------------------
      |     |     |     |     |     |     |     |     |     |     |
SCORE 0     28    57    85    113   142   170   198   227   255
STDEV


                          PARAMETERS

Similarity matrix      Unitary     K-tuple                    2
    atch penalty             1     Joining penalty           20
    penalty               1.00     Window size               32
Gap size penalty          0.05
Cutoff score                 0
Randomization group          0

                       SEARCH STATISTICS

Scores:                    Mean      Median     Standard Deviation
                            255           0                   0.00

Times:                      CPU                  Total Elapsed
                    00:00:00.00                  00:00:00.00

Number of residues:                        255
Number of sequences searched:                1
Number of scores above cutoff:               1


The scores below are sorted by initial score.
Significance is calculated based on initial score.

A 100% identical sequence to the query sequence was not found.


The list of best scores is:
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Sequence Name	Description	Length	Init. Score	Opt. Score	Sig.	Frame
1. US-09-071-710-36	Sequence 36, Application	255	255	255	0.00	0

1. US-593-113 (1-553)
   US-09-071-710-36 Sequence 36, Application US/09071710

Sequence 36, Application US/09071710
Patent No. 6130043
GENERAL INFORMATION:
APPLICANT: BILLING-MEDEL, PATRICIA
APPLICANT: COHEN, MAURICE
APPLICANT: COLPITTS, TRACEY L.
APPLICANT: FRIEDMAN, PAULA N.
APPLICANT: GORDON, JULIAN
APPLICANT: GRANADOS, EDWARD N.
APPLICANT: HODGES, STEVEN C.
APPLICANT: KLASS, MICHAEL R.
APPLICANT: KRATOCHVIL, JON D.
APPLICANT: ROBERTS-RAPP, LISA
APPLICANT: RUSSELL, JOHN C.
APPLICANT: STROUPE, STEPHEN D.
TITLE OF INVENTION: REAGENTS AND METHODS USEFUL
TITLE OF INVENTION: FOR DETECTING DISEASES OF THE PROSTATE
NUMBER OF SEQUENCES: 41
CORRESPONDENCE ADDRESS:
ADDRESSEE: Abbott Laboratories
STREET: 100 Abbott Park Road
CITY: Abbott Park
STATE: IL
COUNTRY: USA
ZIP: 60064-3500
COMPUTER READABLE FORM:
MEDIUM TYPE: Diskette
COMPUTER: IBM Compatible
OPERATING SYSTEM: DOS
SOFTWARE: FastSEQ for Windows Version 2.0
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/09/071,710
FILING DATE:
CLASSIFICATION:
PRIOR APPLICATION DATA:
APPLICATION NUMBER: 08/850,713
FILING DATE: 02-MAY-1997
ATTORNEY/AGENT INFORMATION:
NAME: Becker, Cheryl L.
REGISTRATION NUMBER: 35,441
REFERENCE/DOCKET NUMBER: 6083.US.P1
TELECOMMUNICATION INFORMATION:
TELEPHONE: 847/935-1729
TELEFAX: 847/938-2623
TELEX:
INFORMATION FOR SEQ ID NO: 36:
SEQUENCE CHARACTERISTICS:
LENGTH: 255 amino acids
TYPE: amino acid
STRANDEDNESS: single
TOPOLOGY: linear
MOLECULE TYPE: No. 6130043e

Initial Score = 255 Optimized Score = 255 Significance = 0.00
Residue Identity = 100% Matches = 255 Mismatches = 0
Gaps = 0 Conservative Substitutions = 0

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   250       260       270       280       290       300       310       320
    AFRNLGALLPRLHQLCCRMPRTLRRLFVAELCSWMALMTFTLFYTDFVGEGLYQGVPRAEPGTEARRHYDEG
                                                     ||||||||||||||||||||
                                                     GLYQGVPRAEPGTEARRHYDEG
                                                     X       10        20

           330       340       350       360       370       380       390
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```
VRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVAAFPVAAGATCLSHSVAVVTASAALTGFTFSAL
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VRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVAAFPVAAGATCLSHSVAVVTASAALTGFTFSAL
      30        40        50        60        70        80        90

     400       410       420       430       440       450       460
QILPYTLASLYHREKQVFLPKYRGDTGGASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGAS
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
QILPYTLASLYHREKQVFLPKYRGDTGGASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGAS
   100       110       120       130       140       150       160

   470       480       490       500       510       520       530
ACDVSVRVVVGEPTEARVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIY
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
ACDVSVRVVVGEPTEARVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIY
 170       180       190       200       210       220       230

 540       550  X
FATQVVFDKSDLAKYSA
|||||||||||||||||
FATQVVFDKSDLAKYSA
40        250    X
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44	113.5	4.0	460	4	US-09-252-991A-24308	Sequence 24308, A
45	[redacted]3	3.9	1403	4	US-09-262-537-6	Sequence 6, Appli

ALIGNMENTS

RESULT 1
US-09-020-956-113
; Sequence 113, Application US/09020956
; Patent No. 6261562
; GENERAL INFORMATION:
; APPLICANT: Xu, Jiangchun
; APPLICANT: Dillin, Davin C.
; TITLE OF INVENTION: COMPOUNDS FOR IMMUNOTHERAPY OF PROSTATE CANCER AND METHODS I
; NUMBER OF SEQUENCES: 178
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: SEED and BERRY LLP
; STREET: 6300 Columbia Center, 701 Fifth Avenue
; CITY: Seattle
; STATE: WA
; COUNTRY: USA
; ZIP: 98104
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.30
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/09/020,956
; FILING DATE: 09-FEB-1998
; CLASSIFICATION:
; ATTORNEY/AGENT INFORMATION:
; NAME: Maki, David J.
; REGISTRATION NUMBER: 31,392
; REFERENCE/DOCKET NUMBER: 210121.427C2
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (206) 622-4900
; TELEFAX: (206) 682-6031
; INFORMATION FOR SEQ ID NO: 113:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 553 amino acids
; TYPE: amino acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; MOLECULE TYPE: protein
; ORIGINAL SOURCE:
; ORGANISM: Homo sapiens
US-09-020-956-113

Query Match 100.0%; Score 2861; DB 3; Length 553;
Best Local Similarity 100.0%; Pred. No. 1.1e-270;
Matches 553; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MVQRLWVSRLLRHRKAQLLLVNLLTFGLEVCLAAGITYVPPLLLEVGVEEKFMTMVLGIG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MVQRLWVSRLLRHRKAQLLLVNLLTFGLEVCLAAGITYVPPLLLEVGVEEKFMTMVLGIG 60

Qy         61 PVLGLVCVPLLGSASDHWRGRYGRRRPFIWALSLGILLSLFLIPRAGWLAGLLCPDPRPL 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 PVLGLVCVPLLGSASDHWRGRYGRRRPFIWALSLGILLSLFLIPRAGWLAGLLCPDPRPL 120

Qy        121 ELALLILGVGLLDFCGQVCFTPLEALLSDLFRDPDHCRQAYSVYAFMISLGGCLGYLLPA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 ELALLILGVGLLDFCGQVCFTPLEALLSDLFRDPDHCRQAYSVYAFMISLGGCLGYLLPA 180

Qy        181 IDWDTSALAPYLGTQEECLFGLLTLIFLTCVAATLLVAEEAALGPTEPAEGLSAPSLSPH 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 IDWDTSALAPYLGTQEECLFGLLTLIFLTCVAATLLVAEEAALGPTEPAEGLSAPSLSPH 240

Qy        241 CCPCRARLAFRNLGALLPRLHQLCCRMPRTLRRLFVAELCSWMALMTFTLFYTDFVGEGL 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 CCPCRARLAFRNLGALLPRLHQLCCRMPRTLRRLFVAELCSWMALMTFTLFYTDFVGEGL 300

Qy        301 YQGVPRAEPGTEARRHYDEGVRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 YQGVPRAEPGTEARRHYDEGVRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVA 360

Qy        361 AFPVAAGATCLSHSVAVVTASAALTGFTFSALQILPYTLASLYHREKQVFLPKYRGDTGG 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 AFPVAAGATCLSHSVAVVTASAALTGFTFSALQILPYTLASLYHREKQVFLPKYRGDTGG 420

Qy        421 ASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGASACDVSVRVVVGEPTEA 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 ASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGASACDVSVRVVVGEPTEA 480

Qy        481 RVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIYFATQ 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 RVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIYFATQ 540

Qy        541 VVFDKSDLAKYSA 553
              |||||||||||||
Db        541 VVFDKSDLAKYSA 553
```

RESULT 3
US-09-43[redacted]-113
; Sequence 113, Application US/09439313
; Patent No. 6329505
; GENERAL INFORMATION:
; APPLICANT: Xu, Jiangchun
; APPLICANT: Dillon, Davin C.
; APPLICANT: Mitcham, Jennifer L.
; APPLICANT: Harlocker, Susan Louise
; APPLICANT: Jiang Yuqui
; APPLICANT: Reed, Steven G.
; APPLICANT: Kalos, Michael
; APPLICANT: Panger, Gary
; APPLICANT: Retter, Mark
; APPLICANT: Solk, John
; APPLICANT: Day, Craig
; TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THERAPY AND
; TITLE OF INVENTION: DIAGNOSIS OF PROSTATE CANCER
; FILE REFERENCE: 210121.427C9
; CURRENT APPLICATION NUMBER: US/09/439,313

13;

; CURRENT FILING DATE: 1999-11-12
; NUMBER OF SEQ ID NOS: 575
; SOFTWARE: FastSEQ for Windows Version 3.0
; SEQ ID NO 113
; LENGTH: 553
; TYPE: PRT
; ORGANISM: Homo sapien
US-09-439-313-113

Query Match 100.0%; Score 2861; DB 4; Length 553;
Best Local Similarity 100.0%; Pred. No. 1.1e-270;
Matches 553; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 MVQRLWVSRLLRHRKAQLLLVNLLTFGLEVCLAAGITYVPPLLLEVGVEEKFMTMVLGIG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MVQRLWVSRLLRHRKAQLLLVNLLTFGLEVCLAAGITYVPPLLLEVGVEEKFMTMVLGIG 60

Qy         61 PVLGLVCVPLLGSASDHWRGRYGRRRPFIWALSLGILLSLFLIPRAGWLAGLLCPDPRPL 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 PVLGLVCVPLLGSASDHWRGRYGRRRPFIWALSLGILLSLFLIPRAGWLAGLLCPDPRPL 120

Qy        121 ELALLILGVGLLDFCGQVCFTPLEALLSDLFRDPDHCRQAYSVYAFMISLGGCLGYLLPA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 ELALLILGVGLLDFCGQVCFTPLEALLSDLFRDPDHCRQAYSVYAFMISLGGCLGYLLPA 180

Qy        181 IDWDTSALAPYLGTQEECLFGLLTLIFLTCVAATLLVAEEAALGPTEPAEGLSAPSLSPH 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 IDWDTSALAPYLGTQEECLFGLLTLIFLTCVAATLLVAEEAALGPTEPAEGLSAPSLSPH 240

Qy        241 CCPCRARLAFRNLGALLPRLHQLCCRMPRTLRRLFVAELCSWMALMTFTLFYTDFVGEGL 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 CCPCRARLAFRNLGALLPRLHQLCCRMPRTLRRLFVAELCSWMALMTFTLFYTDFVGEGL 300

Qy        301 YQGVPRAEPGTEARRHYDEGVRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 YQGVPRAEPGTEARRHYDEGVRMGSLGLFLQCAISLVFSLVMDRLVQRFGTRAVYLASVA 360

Qy        361 AFPVAAGATCLSHSVAVVTASAALTGFTFSALQILPYTLASLYHREKQVFLPKYRGDTGG 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 AFPVAAGATCLSHSVAVVTASAALTGFTFSALQILPYTLASLYHREKQVFLPKYRGDTGG 420

Qy        421 ASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGASACDVSVRVVVGEPTEA 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 ASSEDSLMTSFLPGPKPGAPFPNGHVGAGGSGLLPPPPALCGASACDVSVRVVVGEPTEA 480

Qy        481 RVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIYFATQ 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 RVVPGRGICLDLAILDSAFLLSQVAPSLFMGSIVQLSQSVTAYMVSAAGLGLVAIYFATQ 540

Qy        541 VVFDKSDLAKYSA 553
              |||||||||||||
Db        541 VVFDKSDLAKYSA 553
```